UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456
	CIVIL ACTION NO. 01-CV-12257-PBS
THIS DOCUMENT RELATES TO ALL ACTIONS	Judge Patti B. Saris

MEMORANDUM OF BRISTOL MYERS SQUIBB DEFENDANTS IN SUPPORT OF THEIR MOTION TO DISMISS

Defendants Bristol-Myers Squibb Co., Oncology Therapeutics Network Corp. and Apothecon, Inc. ("BMS")[1] join in the Consolidated Memorandum in Support of Defendants' Motion to Dismiss the Master Consolidated Class Action Complaint ("Consolidated Memorandum" or "Consol. Mem."), as well as the memoranda of other defendants raising common issues, and file this memorandum in order to make a number of additional points.

Preliminary Statement

Congress and the Executive Branch have not only known about the "spread" between average wholesale prices ("AWPs") and actual physician costs for many years, they have actually set the reimbursement rates about which plaintiffs complain. This Court cannot award plaintiffs relief on their Class 1 claims without determining that the reimbursement rates established by the government should have been different. For that reason, this action is barred by the filed rate doctrine, the state action doctrine and the doctrines of field and conflict preemption.

[1] Oncology Therapeutics Network Corp. and Apothecon, Inc. are wholly-owned subsidiaries of Bristol-Myers Squibb Co.

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Moreover, not only have Congress and the Executive Branch known about the "spread" between AWPs and actual physician costs for many years, that fact has been widely reported in a variety of publicly available sources. For that reason, plaintiffs' Class 2 claims as well as their Class 1 claims are barred because there can be no intent to defraud when the alleged victim has ready access to the truth. In addition, the enterprises alleged by plaintiffs are defective because plaintiffs have alleged nothing more than a variety of conspiracies, which is insufficient as a matter of law.

Finally, plaintiffs' Class 1 and Class 2 claims with respect to improper use of free samples by BMS are defective because they do not even come close to satisfying the requirements of Fed. R. Civ. P. 9(b). There is no identification of who gave what free sample to whom and when, much less an explanation of why giving the free sample was fraudulent. Plaintiffs' Class 2 claims also fail to satisfy Fed. R. Civ. P. 9(b) because they do not identify the "brand name" drugs that were allegedly part of that scheme.

Statement of Facts

As set forth in the Master Consolidated Class Action Complaint ("Complaint" or "Compl."), the well-pleaded allegations of which must be taken as true for purposes of this motion, plaintiffs purport to represent two classes: (1) Class 1 -- persons who made co-payments for Covered Drugs under Medicare Part B; and (2) Class 2 -- third-party payors, such as health plans, who contracted with pharmacy benefit managers ("PBMs") or other intermediaries to pay for brand name prescription drugs purchased by plan participants. (Compl. ¶ 333.) Plaintiffs contend that the defendant manufacturers, including BMS, violated the Racketeer Influenced and Corrupt Organizations Act ("RICO"), as well as various state consumer protection statutes, by providing "inflated" and "fictitious" AWPs to trade publications such as the Red Book, Blue

Book and Medi-Span. (Id. ¶¶ 3, 158-60.) Plaintiffs contend that they have been damaged because "health care providers . . . are reimbursed by Medicare based on the inflated AWP" (id. ¶ 4) and intermediaries such as PBMs receive payments from third party payors based on "inflated" AWPs (id. ¶¶ 5, 166-72).

Plaintiffs affirmatively allege that "Medicare calculates the 'allowed' amount for the drug". (Compl. ¶ 144.) They also allege: "The Medicare Program has publicly announced that it would use the AWP published in pharmaceutical industry magazines as the basis for reimbursement." (Id. ¶ 147.) Plaintiffs seek damages based on the 20% co-payment that is mathematically derived from the "allowable amount" established by the government for reimbursement purposes. (Id. ¶ 149; see also ¶¶ 368, 395, 422.)

As set forth in the Consolidated Memorandum, there has been extensive public disclosure of the "spread" between AWPs and actual provider costs about which plaintiffs complain. For example, in Louisiana v. Dep't of Health & Human Servs., 905 F.2d 877, 880 (5th Cir. 1990), the court quoted the observation of government sources that "'AWP data are frequently inflated'". In a 1996 "Dow Jones" article to which plaintiffs refer in their Complaint (Compl. ¶ 135), AWP is described as "Ain't What's Paid". Bill Alpert, Hooked On Drugs: Why Do Insurers Pay Such Outrageous Prices For Pharmaceuticals?, Barron's, June 10, 1996, at 16 (appended hereto as Exhibit 1). In a 1997 report, the Office of Inspector General of HHS reported: "The published AWPs that are currently being used by Medicare-contracted carriers to determine reimbursement bear little or no resemblance to actual wholesale prices that are available to the physician and supplier communities that bill for these drugs." Excessive Medicare Payments for Prescription Drugs, Office of Inspector General, Department of Health and Human Services, at ii (Dec. 1997) (appended hereto as Exhibit 2).

Argument

I.

THE COURT LACKS SUBJECT MATTER JURISDICTION OVER THE CLASS 1 CLAIMS BECAUSE THERE IS NO JUSTICIABLE CONTROVERSY.

A. Plaintiffs' Class 1 Claims Are Barred By The Filed Rate Doctrine

The filed rate doctrine provides that "any 'filed rate' -- that is, one approved by the governing agency -- is per se reasonable and unassailable in judicial proceedings [against non-governmental entities] brought by rate-payers." Wegoland Ltd. v. NYNEX Corp., 27 F.3d 17, 18 (2d Cir. 1994). The filed rate doctrine is based on the concept that "(1) legislatively appointed regulatory bodies have institutional competence to address rate-making issues; (2) courts lack the competence to set . . . rates; and (3) the interference of courts in the rate-making process would subvert the authority of rate-setting bodies and undermine the regulatory regime." Sun City Taxpayers' Ass'n v. Citizens Utils. Co., 45 F.3d 58, 62 (2d Cir. 1995).[2] While the filed rate doctrine originally arose in the context of antitrust cases against railroads and utilities, see, e.g., Keogh v. Chicago & N.W. Rwy. Co., 260 U.S. 156, 163 (1922), it is clear that it applies to RICO cases, see, e.g., Taffet v. The Southern Co., 967 F.2d 1483, 1488-90 (11th Cir. 1992), and to industries other than railroads and utilities. See, e.g., Square D Co. v. Niagara Frontier Tariff Bureau, Inc., 476 U.S. 409 (1986) (freight transportation); Fersco v. Empire Blue Cross/Blue Shield of New York, 93 Civ. 4226 (JFK), 1994 WL 445730 (S.D.N.Y. Aug. 17, 1994) (health insurance); Servais v. Kraft Foods, Inc., 631 N.W.2d 629 (Wis. Ct. App. 2001), aff'd, 643 N.W.2d 92 (Wis. 2002) (milk prices). See generally Korte v. Allstate Ins. Co., 48 F. Supp. 2d

[2] Courts defer to regulatory bodies in this context, in part, because the regulatory body is not a party to the action. Plaintiffs always have the option of asserting a claim against the rate-setting body directly, in which case the degree of deference would be different.

647, 651 (E.D. Tex. 1999) ("While the filed rate doctrine had its origins in the area of the common carrier, it has subsequently been extended to a number of regulated industries").

There can be no doubt that the filed rate doctrine applies to this case. The rates in question -- the "allowed amounts" for reimbursement under Medicare -- were determined by the government. While plaintiffs allege that the government based its reimbursement rates on AWPs that were fraudulent, "every court that has considered the . . . argument has rejected the notion that there is a fraud exception to the filed rate doctrine." Wegoland, 27 F.3d at 20.

This Court's decision in Town of Norwood v. New England Power Co., 23 F. Supp. 2d 109 (D. Mass. 1998) is instructive. In Norwood, a town that owned and operated an electric distribution system sued its wholesale power supplier complaining that the supplier was charging the town substantially higher rates than it was charging its own affiliates. Noting that "a federal district court cannot make its own determination of what rate is 'just and reasonable,'" the Court dismissed the town's antitrust claim on the ground that it was barred by the filed rate doctrine. Id. at 116. The Court observed that "[t]he filed rate doctrine is applied 'out of deference to a congressional scheme of uniform regulation' in order to avoid 'impermissibly usurp[ing] a function that Congress has assigned to a federal regulatory body.'" Id. Quoting from the Eighth Circuit's decision in H.J. Inc. v. Northwestern Bell Tel. Co., 954 F.2d 485, 488 (8th Cir. 1992), the Court added: "Even if plaintiff's complaint refers to some underlying or distinct conduct, '[t]he filed rate doctrine prohibits a party from recovering damages measured by comparing the filed rate and the rate that might have been approved absent the conduct in issue.'" Id. at 116-17.

On appeal, the First Circuit affirmed this branch of the Court's decision[3] because the rates in question were subject to agency regulation. 202 F.3d 408, 418 (1st Cir. 2000). In response to the argument that the agency had not even considered certain cost data, the First Circuit stated: "It is the filing of the tariffs, and not any affirmative approval or scrutiny by the agency, that triggers the filed rate doctrine." Id. at 419 (emphasis omitted).[4] The court went on to rule that claims for declaratory and injunctive relief, as well as damages, were barred because "any meaningful relief . . . would require the alteration of tarrifs . . . ." Id. at 420.

This case is even stronger than Norwood because, here, the reimbursement rates at issue were not merely submitted to the government, they were set by the government.[5] There is no way the Court can grant plaintiffs relief without deciding that the "allowed amounts" should have been different. Where "damages can only be measured by comparing the difference between the rates the [government] originally approved and the rates the [government] should have approved absent the conduct of which the class complains," there is no justiciable controversy. H.J. Inc., 954 F.2d at 494.

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[3] The First Circuit reversed and remanded that portion of this Court's decision which held that the plaintiff's Clayton Act § 7 claim (challenging a merger) was barred by the filed rate doctrine, ruling that the filed rate doctrine did not apply to that claim since the claim did not require the Court to sit in judgment of an administratively approved price. 202 F.3d 408, 422 (1st Cir. 2000).

[4] This language from the First Circuit's opinion does not imply that the rate must be lodged with a government office for the filed rate doctrine to apply. The court was making the point that acceptance of the rate without disapproval was sufficient. See also Kline and Co. v. MCI Communications Corp., 98 F. Supp. 2d 69, 73 (D. Mass. 2000) (agency need not conduct "meaningful review" of rates for filed rate doctrine to apply). It is also clear that where a rate is "approved by the governing regulatory agency", that is sufficient as well. Wegoland, 27 F.3d at 18. As the Supreme Court has held, it is of no significance to the doctrine whether the rate in question is (i) filed by a private party and merely "accepted" by the regulator or (ii) "determine[d]" or "fixed" by the regulator itself. Montana-Dakota Utils. Co. v. Northwestern Pub. Serv. Co., 341 U.S. 246, 251-52 (1951).

[5] In Norwood, the defendant proposed a rate that was accepted by the agency. Here, after considerable scrutiny, the agency charged with establishing the rate affirmatively adopted AWP, as reported in publications such as the Red Book, in establishing the "allowed amount" for Medicare drugs.

B. Plaintiffs' Class 1 Claims Are Barred By The "State Action" Doctrine

Under Parker v. Brown, 317 U.S. 341 (1943) and Eastern Railroad Presidents Conf. v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961), where a plaintiff's injury is the direct result of governmental action, there can be no claim against private parties who caused or influenced the government to take that action. See also Massachusetts School of Law at Andover, Inc. v. American Bar Ass'n, 107 F.3d 1026, 1036-37 (3d Cir. 1997) (ABA's law school accreditation rules, even if anticompetitive, are not actionable because it is the States, not the ABA, that incorporate the accreditation rules into bar admission requirements); Sandy River Nursing Care v. Aetna Casualty, 985 F.2d 1138, 1146 (1st Cir. 1993) (employers paying higher workers compensation insurance rates will not be heard to complain that insurers influenced state to "move[] away from the state's previous pro-competitive policy toward rate setting.").[6]

Accordingly, Medicare Part B co-payors cannot sue drug manufacturers for providing to publications allegedly false AWPs because it was the government that affirmatively decided (with full knowledge of the public record) to make those AWPs the basis for government reimbursement and the co-payment. Indeed, even if one assumes (incorrectly) that defendants have defrauded the government program, Medicare, thereby harming private co-payors, numerous cases have held that such a fraud claim is barred under the principles of Parker and Noerr.[7] See, e.g., Armstrong Surgical Cen. v. Armstrong Cty. Mem. Hosp., 185 F.3d 154,

[6] While Noerr immunity claims typically arise in the context of antitrust actions, the state action doctrine is applicable to RICO actions and to state-law claims. International Bhd. of Teamsters v. Philip Morris, Inc. 196 F.3d 818, 826 (7th Cir. 1999); Bath Petroleum Storage, Inc. v. Market Hub Partners, L.P., 129 F. Supp. 2d 578, 593-97 (W.D.N.Y.), aff'd, 229 F.3d 1135 (2d Cir. 2000).

[7] The government's knowledge about AWP and its policy reasons for using it for Medicare purposes (i.e. allowing medical providers' profits on drugs to "cross-subsidize" inadequate payments for providers' related services) implicate another related antitrust standing argument based on the Supreme Court's decision in California Retail Liquor Dealers Ass'n v. Midcal Aluminum, Inc., 445 U.S. 97 (1980). In brief, Midcal and its progeny hold that

160-63 (3d Cir. 1999) (plaintiff does not have standing to sue defendants for false filings before state health officials that allegedly cause officials' denial of plaintiff's application); Bristol-Myers Squibb Co. v. Immunex Corp., 84 F. Supp. 2d 574, 577 (D.N.J. 2000) (rejecting drug company's allegation that competitor obtained exclusive drug rights through false statements made to regulators; holding there is "[no] liability on Bristol for acts undertaken by the government. Here, the [NCI] and the [FDA] directly caused [the complained-of] injuries."); see also Midland Export Ltd. v. Elkem Holding, Inc., 947 F. Supp. 163, 166 (E.D. Pa. 1996) ("Even though the ITC reached [its] conclusion allegedly in reliance on market information distorted by Defendants' conspiracy . . . the ITC's action was still the direct cause of the harm here."). The direct cause of plaintiffs' harm is the government, not any action of defendants.

C. Plaintiffs' Class 1 Claims Are Barred By The Doctrine of Preemption

Although the "preemption" doctrine is most often associated with federal supremacy over state statutes and judicial proceedings, it can also apply within the federal system to bar actions under general federal statutes. Amalgamated Ass'n of Street, Elec. Rwy. And Motor Coach Employees v. Lockridge, 403 U.S. 274, 285-288 (1971); Tamburello v. Comm-Tract Corp., 67 F.3d 973, 976 n.2 (1st Cir. 1995). Thus, courts have found that RICO claims have been preempted by federal regulatory schemes in a number of areas. See, e.g., Kenty v. Bank One, 92 F.3d 384, 391-393 (6th Cir. 1996) (McCarran-Furguson Act preempts RICO claims based on alleged fraud relating to insurance); Bodimetric Health Servs., Inc. v.

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private parties are immune from federal antitrust liability if (a) an appropriate legislative or regulatory body has "clearly articulated" a "permissive policy" toward the conduct at issue and (b) the policy is "actively supervised" by the legislature/regulator. See generally II ABA Section of Antitrust Law, Antitrust Law Developments, 1074-1083 (4th ed. 1997). Here, the literally decades of legislation, regulation, studies and debate on AWP's role in Medicare more than satisfy the tests.

Aetna Life & Casualty, 903 F.2d 480, 486-87 (7th Cir. 1990) (RICO claims preempted by administrative benefits determination procedure under the Social Security Act); Jarman v. United Indus. Corp., 98 F. Supp. 2d 757, 765-66 (S.D. Miss. 2000) (claim that pesticide manufacturers had intentionally mislabeled products in violation of RICO preempted as inconsistent with regulatory structure for pesticides created by Congress and jurisdiction of EPA); Norman v. M.S. Carriers, Inc., 741 F. Supp. 148, 149-50 (W.D. Tenn. 1990) (Surface Transportation Assistance Act bars RICO claims based on defendants' alleged violations of federal motor safety regulations). Courts have also found that the Medicare Act can preempt other federal statutes. See St. Vincent's Medical Center v. United States, 32 F.3d 548, 549-50 (Fed. Cir. 1994) (Medicare Act preempts Tucker Act). Furthermore, a specific statutory/administrative construct can preempt federal private lawsuits under a generic statute like RICO "even when the [preemptive] statute provides no alternative remedy," Orsay v. United States, 289 F.3d 1125, 1128-29 (9th Cir. 2002), although in this case there is an administrative remedy. See 42 C.F.R. §§ 405.801-77.

1. Field Preemption

With respect to field preemption, Congress of California Seniors v. Catholic Healthcare West, 87 Cal. App. 4th 491 (Cal. Ct. App. 2001) is on point. In that case, the plaintiff brought a fraud claim on behalf of consumers alleging that a hospital had improperly inflated reimbursement requests under Medicare Part A by including anti-union expenses in its cost reports. Noting that "there is no express preemption in the Medicare statute", the court nevertheless held that the claim was barred by the doctrine of field preemption because (1) Congress had granted broad discretion to the Secretary of HHS to determine reasonable costs; (2) there were various mechanisms available for appealing reimbursement disputes; and (3) the

plaintiff, in effect, was asking the court to review decisions made by the Secretary or his agents. 87 Cal. App. 4th at 499, 502, 509-10.

The only difference between California Seniors and this case is that the former involved claims under Medicare Part A (in-hospital services) while the latter involves claims under Medicare Part B (outpatient services). In this case, as in California Seniors, (1) Congress has authorized an administrative agency to determine reimbursement rates (although it has restricted the agency's discretion); (2) as noted by the court in California Seniors, "Part B disputes may be administratively appealed by the beneficiary or his assignee", 87 Cal. App. 4th at 502; and (3) plaintiffs are asking this Court to review decisions made by the agency and its agents. In this context, any distinction between Part A and Part B is a distinction without a difference; therefore, plaintiffs' federal and state claims on behalf of the Medicare class should be dismissed.

2. Conflict Preemption

With respect to conflict preemption, Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001) is also applicable here. In Buckman, the plaintiffs claimed that they were injured as a result of a fraud on the FDA. The Supreme Court ruled that the claim was barred by the doctrine of conflict preemption because "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and . . . this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives". 531 U.S. at 348.

Here, too, the Executive Branch has the power to deal with allegedly fraudulent AWPs if it chooses to do so. Indeed, plaintiffs have sought production of documents relating to various government investigations. Plaintiffs should not be permitted to pursue their Class 1

claims as surrogates of the government, making claims and policy judgments that the Executive Branch is perfectly capable of making for itself.

II.

PLAINTIFFS' CLASS 1 AND CLASS 2 RICO CLAIMS ARE SUBSTANTIVELY DEFECTIVE AND FAIL TO SATISFY RULE 9(b).

A. Public Knowledge Of The "Spread" Negates Fraudulent Intent

As the Consolidated Memorandum makes clear, there can be no wire fraud or mail fraud to support a RICO claim without a credible allegation that defendants "intended to deceive" those responsible for administering the Medicare system and private health plans in reporting prices to the publications. Even though the First Circuit has stated that reliance is not a necessary element of a mail fraud claim, Systems Mgmt., Inc. v. Loiselle, 303 F.3d 100, 104 (1st Cir. 2002), "a demonstrated intent to deceive is required". United States v. Sawyer, 85 F.3d 713, 732 (1st Cir. 1996).[8] Here, plaintiffs cannot demonstrate the requisite intent because it is undisputed that the "spread" between AWPs and actual provider costs was widely reported in government publications, judicial decisions and media reports which any pharmaceutical manufacturer would have assumed that the plaintiffs in this case -- who include sophisticated health care plans -- would have seen.

As a matter of law, there can be no fraud where the defendant reasonably believes that the alleged victim knows the truth. See, e.g., United States v. Pendergraft, 297 F.3d 1198, 1209 (11th Cir. 2002) ("If [defendants] knew that they could not deceive [the alleged victim], then they could not have had an intent to deceive."); Norton v. United States, 92 F.2d 753, 755

[8] This argument does not focus on whether the victim of the alleged fraud changed position based on the statements made, but rather whether the defendant-speaker can be said to have the requisite state of mind for fraud in the context of information in the public domain.

(9th Cir. 1937) ("There can be no intent to deceive where it is known to the party making representation that no deception can result."). While a defendant's intent is ordinarily a question of fact, where, as here, it is undisputed that the "true" facts were readily available, a plaintiff cannot demonstrate fraudulent intent. See, e.g., United States v. Brown, 79 F.3d 1550, 1556-59 (11th Cir. 1996) ("A 'scheme to defraud' under the pertinent criminal statutes has not been proved where a reasonable juror would have to conclude that the representation is about something which the customer should, and could, easily confirm -- if they wished to do so -- from readily available external sources [real estate brokers or newspaper advertisements]."); Alexander v. The Turner Corp., 00 Civ. 4677, 2001 WL 225049, at *5 (S.D.N.Y. Mar. 2, 2001) ("Plaintiff cannot show misrepresentation or intent to misrepresent when the alleged fraudulently concealed information was contained in a publicly available document [a proxy statement]."). Furthermore, it does not matter whether the plaintiff actually saw the publicly available information; the existence of the information negates any inference of bad faith. Cf. United States v. Josleyn, 99 F.3d 1182, 1194 (1st Cir. 1996) (defendant had no obligation to prove that alleged victim actually condoned the activities in question; the burden is on the government to prove "fraudulent intent and the consequent lack of good faith").[9]

This analysis in the context of a motion to dismiss is similar to the analysis that courts frequently use in determining whether to grant a motion to dismiss on statute of limitations grounds. See, e.g., Donahue v. Federal Bureau of Investigation, 204 F. Supp. 2d 169,

[9] As materials that plaintiffs have filed with the Court make clear, competition among pharmaceutical manufacturers based on the "spread" is not the product of any fraudulent intent; once the government decides to base reimbursement rates on AWPs as opposed to actual provider costs, the pharmaceutical companies have no choice but to compete on the basis of the spread. If they do not, they will not get any business. See Kalb, Bass & Fabrikant, The Average Wholesale Price: It Ain't What The Government Wants To Pay, BNA Health Law Reporter, Vol. 10, No. 9 (March 1, 2001), annexed to the Affidavit of Thomas Sobol, sworn to October 16, 2002, as Exhibit 4.

177 (D. Mass. 2002) ("[S]ome cases hold that media reports, in some circumstances, provide the plaintiffs with constructive notice of their claims".). Where a newspaper article or other publicly available information would alert a reasonable person to the possibility of fraud, the court may dismiss the action even if the plaintiff claims that it did not see the information. See, e.g., In re Sterling Foster & Co. Sec. Lit., --- F. Supp. 2d ---, 2002 WL 1395448, at *7 (E.D.N.Y. June 27, 2002) (lawsuits and newspaper articles); In re Ultrafem Inc. Sec. Lit., 91 F. Supp. 2d 678, 692 (S.D.N.Y. 2000) (Bloomberg news article); Blue Cross of California v. SmithKline Beecham Clinical Labs., Inc., 108 F. Supp. 2d 116, 123-24 (D. Conn. 2000) (media stories and government reports). The court may decide the issue on the basis of the undisputed facts. See Hodas v. Sherburne, Powers & Needham, P.C., 938 F. Supp. 60, 64-65 (D. Mass. 1996) aff'd per curiam 114 F.3d 1169 (1st Cir. 1997) (RICO claim dismissed where undisputed facts demonstrated that plaintiff was on notice of the possibility of fraud).

There are numerous Court of Appeals cases interpreting the False Claims Act, 31 U.S.C. § 3729 et seq., which hold that "prior government knowledge of an allegedly false claim can negate the scienter required for an FCA violation." United States ex rel. Becker v. Westinghouse Savannah River Co., 303 F.3d 284, 289 (4th Cir. 2002) (cataloging cases).[10] Since the "scienter requirement [under the FCA] is something less than that set out in the common law" (and therefore is also less than the scienter requirement for statutory mail and wire fraud), Wang v. FMC Corp., 975 F.2d 1412, 1420 (9th Cir. 1992) (emphasis added), it follows that

[10] In Becker, the defendant government contractor, Westinghouse, was alleged to have knowingly disregarded Congressional appropriations rules for an energy project. The court noted that the Department of Energy "had at least as much knowledge as [the contractor] Westinghouse regarding Congressional authority", id. at 288, and that "DOE's full knowledge of the material facts . . . negates any knowledge that Westinghouse had regarding the truth or falsity of those representations." Id. at 289.

plaintiffs in this case cannot possibly show that defendants acted with the requisite "intent to deceive" to support their claim under RICO. Indeed, while the existence of publicly available information negates fraudulent intent for both the Class 1 and Class 2 claims, it would be completely anomalous for the Class 1 plaintiffs to be able to pursue a claim based on their 20% co-payment under circumstances in which the government, which pays 80% of the reimbursement, could not pursue a claim itself.

B. An Enterprise Must Be Something More Than A Conspiracy

With respect to plaintiffs' provider, publisher and PBM enterprises, plaintiffs repeat the mantra that they are "ongoing and continuing business organizations consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering" drugs. (E.g., Compl. ¶¶ 346, 375, 402, 429.) While courts have struggled with the proper definition of an enterprise, it is clear that an enterprise must be something more than a conspiracy -- i.e. its members must exhibit some form of organization in addition to a "common purpose". See, e.g., Stachon v. United Consumers Club, Inc., 229 F.3d 673, 675-76 (7th Cir. 2000) ("To withstand Appellees' motion to dismiss, however, Appellants must present something more than . . . assertions of conspiracy; otherwise, 'every conspiracy to commit fraud that requires more than one person to commit is a RICO organization and consequently every fraud that requires more than one person to commit is a RICO violation.'"); Chang v. Chen, 80 F.3d 1293, 1300 (9th Cir. 1996) ("A conspiracy . . . is not an enterprise for purposes of RICO."); see also United States v. Patrick, 248 F.3d 11, 17 (1st Cir.) (plaintiff must prove "that the alleged enterprise had an ongoing organization, formal or informal, and that its various associates functioned as a continuing unit for a common purpose"), cert.

denied sub nom. Arthur v. United States, 122 S. Ct. 620 (2001) and cert. denied, Patrick v. United States, 122 S. Ct. 1215 (2002) (emphasis added).

C. The Complaint Fails to Satisfy Rule 9(b) With Respect To BMS

Plaintiffs allege that BMS "used free drugs and other goods to encourage participation by physicians." (Compl. ¶ 244.) Other than (a) one example of BMS allegedly providing a free drug to induce two oncologists to purchase other BMS drugs and (b) the practice of giving doctors "Cytoguards", a device used to prevent spilling of the drugs given intravenously to patients, there are no facts pled to support this allegation; nor is there any explanation of what physicians are being encouraged to "participate" in (other than purchasing BMS products). In short, nothing in the complaint is pled to suggest why these two acts might be deemed wrong, let alone fraudulent.[11]

RICO allegations that do not specify what conduct was fraudulent, why the conduct was fraudulent, how the fraudulent conduct was carried out and when and where the fraudulent conduct took place must be dismissed. M&I Heat Transfer Products, Ltd. v. Willke, 131 F. Supp. 2d 256, 261 (D. Mass. 2001). As the Schering-Plough/Warrick defendants make clear in their motion to strike paragraphs 155-56 of the complaint, this is not a case like Lupron where manufacturers are alleged to have encouraged doctors to bill the government for free samples.[12] Indeed, BMS stands accused of nothing more than good salesmanship.

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[11] Nor is there any allegation of how the mails or wires were used in connection with these free samples. North Bridge Associates, Inc. v. Boldt, 274 F.3d 38, 44 (1st Cir. 2001) (dismissing RICO claims because complaint did not allege facts that implicated the use of the mails or wires).

[12] BMS joins in the Schering-Plough/Warrick defendants' motion to strike and for a more definite statement. BMS also joins the other defendants' motions to dismiss claims for lack of standing, where no named plaintiff has paid for a defendant's drug. No Class 1 plaintiff is alleged to have paid for a BMS drug.

Plaintiffs also fail to identify the "brand name" prescription drugs that are the subject of their Class 2 claims. There are literally hundreds of drugs that could fit that description, depending on how the term "brand name" is defined. BMS cannot begin to prepare a defense until it knows what plaintiffs are talking about.

Conclusion

For the foregoing reasons, the Complaint should be dismissed.

Respectfully submitted,

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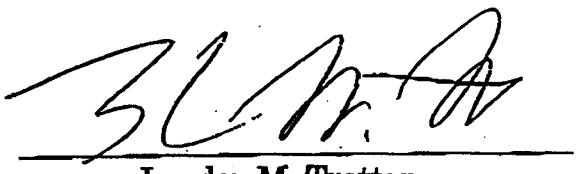
Dated: November 4, 2002

CERTIFICATE OF SERVICE

I, Lyndon M. Tretter, certify that a true and correct copy of the foregoing motion and memorandum of law was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on Nov. 4, 2002, a copy to Verilaw Technologies for posting and notification to all parties.



Lyndon M. Tretter

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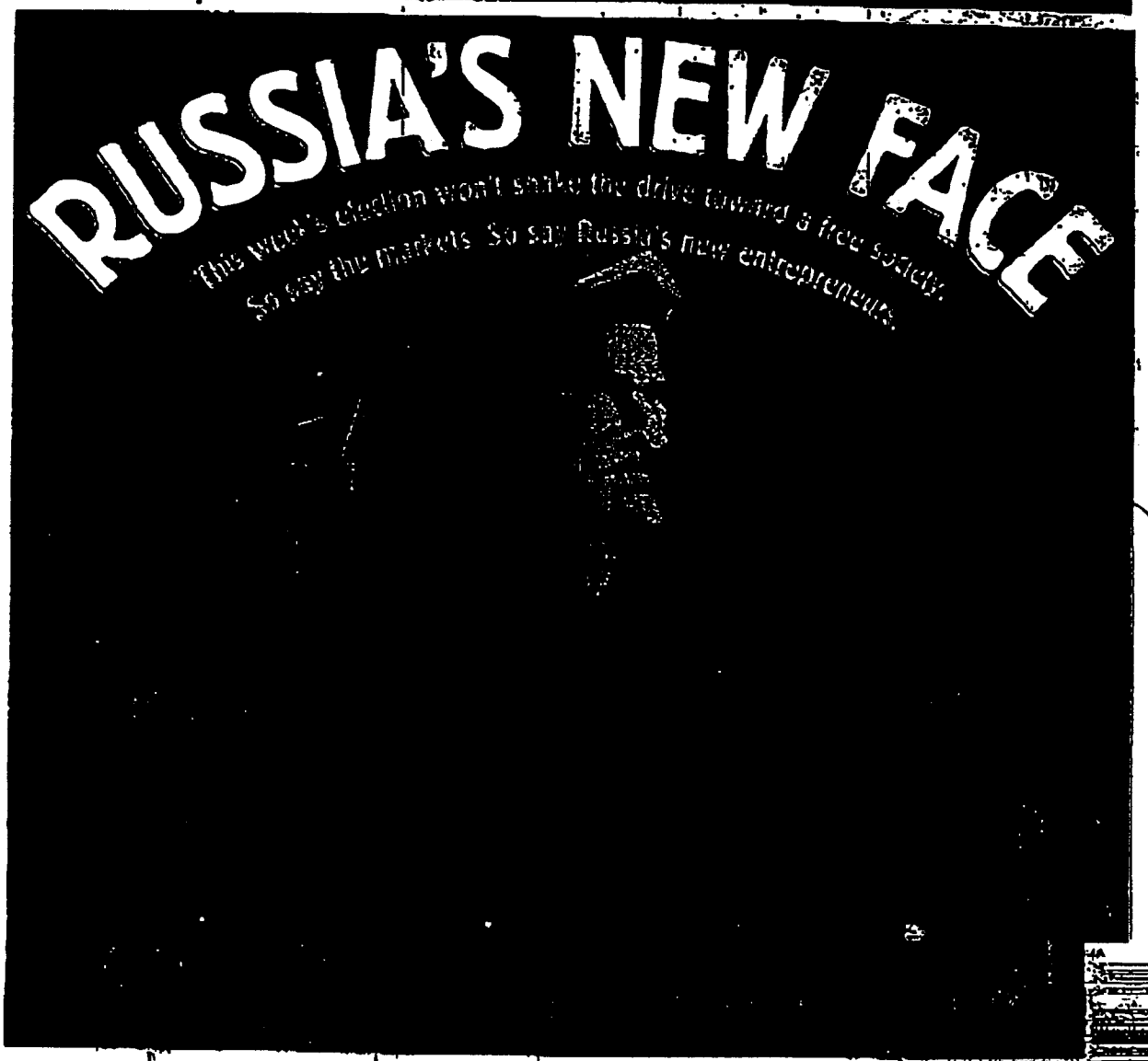

June 10, 1996 BARRON'S

Hooked on Drugs

Why do insurers pay such outrageous prices for pharmaceuticals?

BY BILL ALPERT • Jim Fanning saw the plaque in a doctor's splendid home: "This is the house that leucovorin built." Leucovorin is one of the cancer drugs that typifies a basic drug-industry pricing convention that, in Fanning's view, is a multibillion-dollar fraud. Fanning, the pharmacy director of Fort Worth-based ChemoLab, isn't alone in criticizing the published wholesale prices that most insurers, public and private, use in determining how much to pay for pharmaceuticals. For many drugs, especially the growing number coming off patent and going generic, the drug providers actually pay wholesale prices that are 60%-90% below the so-called average wholesale price, or AWP, used in reimbursement claims.

But Medicare, one of the largest insurers that still reimburses at AWP, is about to demand a change. The huge federal health-insurance program, trying to forestall insolvency, soon will propose regulations aimed at cutting the amount it lays out for the nearly $2 billion in annual drug claims it covers outside of hospitals. The move – especially if it is followed by others now paying near AWP for drugs – will attack from a new direction the pricing practices of a drug industry already beset by antitrust suits from retail druggstores. It also could upset a large segment of the health-care industry, which has thrived on the huge spread between the published wholesale prices used in insurance claims and the far lower wholesale prices actually paid.

That segment includes oncology practices, respiratory therapy firms and home-infusion companies. It also includes the drug makers themselves, whose allegedly inflated price lists and the opportunity for profiteering that they afford to middlemen, gain them market share and encourage overuse of their products. Among the publicly traded companies that could be affected: Apria Healthcare Group, Lincare Holdings, RoTech Medical, OmniCare, Abbott Laboratories and Baxter International.

Most people don't even know that Medicare pays for pharmaceuticals and related products, but through piecemeal congressional authorizations, the program now covers certain drugs for emphysema, cancer, kidney dialysis and organ transplantation, often requiring injection. While still barely 1% of its nearly $184 billion in 1995 spending, Medicare's outpatient drug bill (not including co-payments) was $1.8 billion last year, double 1992's level.

Under its current regulations, Medicare provides reimbursement for those drugs at the lesser of either its estimate of what the drugs cost the doctors or the Average Wholesale Price.

But Medicare's attempts to survey doctors for their costs have been stymied by federal paperwork rules, so it reimburses at the AWP.

Like most drug buyers focused on average wholesale price, Medicare looks to compendia such as the *Red Book*, put out monthly by Medical Economics, of Montvale, N.J., or the rival Blue Book published by First DataBank, a Hearst subsidiary in San Bruno, Calif. Only after Medicare's drug bill started to rocket did policy makers at the Department of Health and Human Services start closely scrutinizing their AWP payments.

They've asked the department's inspector general's office to examine how Medicare suppliers' true acquisition costs square with the program's reimbursement levels.

Claims for nebulizer drugs, the inhalants used by many asthma and emphysema sufferers, were the first studied by the auditors. From under $80 million in 1992, Medicare's annual bill for inhalation drugs grew to $250 million last year, most of it for a steroid called albuterol sulfate.

In a report released Thursday, the inspector general's office stated that the medical-equipment firms that Medicare reimburses at an average wholesale price-derived 40-43 cents per milliliter actually paid less than half that, on average: just 19 cents.

The report asserted that Medicare could have saved about $94 million if its reimbursements had been based on actual wholesale prices over the 14 months covered by the study.

Another report by the inspector general produced a similar finding for feeding-tube liquids, like the market-leading Ensure products of Abbott Labs. These, the IG found, cost nursing homes 42% less than the price that Medicare bases its reimbursements on. Such products cost Medicare and its beneficiaries several hundred million dollars a year.

The inspector general currently is looking at prices for big-ticket drugs and intravenous liquids, too. *Barron's* has done the same, in an examination of the top 20 Medicare drugs (which account for about 75% of the program's drug spending), as well as for various intravenous solutions. Our study shows that for many drugs coming off-patent, the average wholesale prices in no way represents the true wholesale price.

For about 300 dose forms of the drugs, *Barron's* got the AWPs from the *Red Book* and the *Blue Book*. Then, we collected current quotes or price lists from several leading wholesaler specializing in sales to doctors, home health firms, nursing homes and hospitals.

These wholesalers included: The Oncology Therapeutics Network, a South San Francisco-based joint venture of Bristol-Myers Squibb and Axion; Florida Infusion Services of Palm Harbor, Fla.; National Specialty Services, of Nashville; and UltraCare, of Overland Park, Kan. Prices also came in from the Boulder, Colo., hospital buying group Vista Purchasing Partners.

This sampling showed that for single-source drugs still enjoying patent protection, such as Bristol-Myers Squibb's Taxol or Platinol, true wholesale prices are generally 10%-20% below published AWPs.

But for generic drugs, nearly every manufacturer's price was 60%-85% below the published average wholesale price. Some of the generics account for significant spending by Medicare, claiming half of the top 20 slots. Two of them, albuterol and leucovorin, are in the No. 2 and No. 5 slots, respectively.

Pricing is even more unreal worse for intravenous nutritionals and solutions, a category dominated by Abbott Laboratories and Baxter International. Catalog wholesale prices for these items are, on average, 80%-93% below these companies' AWPs.

The prices from the different wholesalers were closely bunched. "There are really no special deals out there," contends Fanning, who buys plenty of drugs at wholesale himself.

If most health-care providers can get these prices, is it any wonder an industry wag says that AWP really means "Ain't What's Paid"?

The high prices on generic drugs have led investigators to seek the source of the published AWPs. Back in 1992, major drug manufacturers told the inspector general's office that the *Red Book*, not the manufacturers, determined the AWP. But *Red Book* officials blamed the manufacturers.

The answers are the same today.

Phil Southerd, associate product manager of the *Red Book*, says it publishes prices that are faxed right from

AWP: AIN'T WHAT'S PAID

▶ A sample of drugs whose published Average Wholesale Price is wildly above the wholesale price available to almost any buyer. Some of these AWPs actually have risen, while real wholesale prices have plummeted. Publishers say drug makers dictate AWPs.

Drug	Use	Maker	'95 AWP	Wholesale Price	% Under AWP
Daunorubicin HCl, powder, 10 mg injectable	Chemotherapy	Adria Labs*	$46 00	$13.00	72%
Etoposide 100 mg in 5 ml for injection	Chemotherapy	Gensia	141 97	34 00	76
Gentamicin Sulfate, 100 mg in 10 ml injection	Antibiotic	Abbott	6 18	1 26	80
Intravenous Immune Globulin, 10 mg	Chemotherapy	Baxter	640 71	266 00	58
Leucovorin Calcium, 350 mg injection	Chemotherapy	Immunex	137 94	22 50	84
Methotrexate 250 mg injection	Chemotherapy	Chiron	26.88	6 40	76
Vancomycin HCl 5 gm in 100 ml injection	Antibiotic	Abbott	135 99	36 00	74
Vincristine Sulfate 1 mg injection	Chemotherapy	Eli Lilly	34 62	6 72	81
8.5% Amino Acid sol., 1000 ml for parenteral nutr.	TPN	Abbott	152 65	10 81	93
50% Dextrose Sol., 500 ml in glass	Intravenous Sol	Baxter	27 03	2 56	91
Lactated Ringer's Injection, 500 ml	Intravenous Sol	Baxter	11 16	1 61	86
Normosol 500 ml	Intravenous Sol	Abbott	16.86	2 04	88
Potassium Phosphate, 15 ml vial	Intravenous Sol	Abbott	5 55	0 48	91

* Unit of Pharmacia-Upjohn

the manufacturers. "They're not our prices," he insists.

Ed Edelstein, *Blue Book* editor, says that, while some brand-name firms don't give him prices, generic firms do. "The AWP is the manufacturer's suggested wholesale price," he says. "It's our editorial policy to go along with that."

But Immunex, with a thriving generic cancer-drug business, says its average wholesale prices aren't its own. "The drug manufacturers have no control over the AWPs published . . . ." says spokeswoman Valerie Dowell.

A maker of generic inhalants gives a different answer, but off the record: "The AWPs typically originate with the manufacturer."

More puzzling is the way generic AWPs stay at their lofty perches, or even rise, as competition forces a drug's true wholesale price into the abyss. "The reason this is happening," suggests Michael Neff, pharmacy program administrator of Medi-Cal, California's Medicaid agency, "is that most folks in a position to pay – even state Medicaid programs and HMOs – generally use AWP as a benchmark for reimbursement."

In 1993, the Bristol-Myers Squibb cancer drug Vepesid came off-patent, opening the market for a generic form called etoposide. A 100-milligram dose of Vepesid had an AWP of about $136. The first generic etoposide was Gensia Pharmaceutical's, with a market price of about $75, but the AWP of $142.

The second generic to market, from Pharmacia, pushed the market price to $60, but Pharmacia set an AWP around $140. Today, the market price for 100 milligrams of etoposide is around $35, but Gensia actually raised its AWP last year by about 10%.

When some drug salespeople visit a doctor, says another Medicaid administrator, the salesperson lets the doctor know that his product has a bigger spread between AWP and the real price than any other generic firm.

If manufacturers deliberately maintain lofty AWPs on their generic drugs, it directly profits their customers, not them. Of course, the drug makers might then gain market share and higher sales from their customers' over-utilization.

Indeed, for makers of generics, unreal average wholesale prices pose a classic social dilemma. If some, but not all, rectify their AWPs, the honest makers cut their own throats. "Manufacturers have told me that if they act on their own they'll dry up their own business," says Medi-Cal's Neff. "If I'm a buyer and one drug gives me 20% higher reimbursement, who am I going to go with?"

Some insurers, including Medicare, decree maximum prices for each generic drug, to avoid the alleged manipulation of AWPs. But it takes a year or so to establish a maximum price for new generics, and insurers haven't gotten around to setting prices for many doses.

"There definitely is over-utilization of these products," acknowledges a maker of inhalation drugs. "Because HCFA [the Health Care Financing Administration, the federal Medicare-Medicaid agency] is paying a somewhat arbitrary price, this has been discussed for almost three years."

FALSE CLAIMS?

▶Some of these firms make drugs, or bill insurers for drugs, that cost far less than the published Average Wholesale Price that Medicare and other insurers pay on claims. Says one wholesaler: "It may be legal, but it's certainly not ethical."

Company	Symbol	Exchange	Recent Price	Medicare Reimbursement Change Might Affect
Abbott Labs	ABT	NYSE	43⅜	Medicare buys $500 million of Lupron, also $100-all-millions of nutritionals
American Home Prods	AHOM	NNM	45½	Medicare/Medicaid pay for 60% of firm's respiratory and infusion services revenues
American Oncology Resources	AONI	NNM	4¼	One-third of revenues from Medicare/ Medicaid; chemo drugs a big profit center
Amgen	AMGN	NNM	60⅞	$75 million in Medicare payments for Neupogen = 10% of drug's U.S. sales
Baxter International	BAX	NYSE	46⅞	Government demands rationale for its published prices on intravenous products
Bristol-Myers Squibb	BMY	NYSE	88⅜	Cancer drugs a mainstay; Medicare bought about 25% of U.S. sales of Taxol
Chiron	CHIR	NNM	97	Cancer drugs approx 5% of sales
Coram	CRH	NYSE	4½	One-third of revenues from nutritional therapy; 27% of payments from Medicare/Medicaid
Gensia	GNSA	NNM	5⅞	Largest product is generic etoposide; just got approval for generic doxorubicin
Immunex	IMNX	NNM	15½	Cancer collaboration with American Home Products; Imuvovirin a $20 million product
Lincare Holdings	LNCR	NNM	41¾	60% of revenues from Medicare/Medicaid, who are other firm's 35% gross margins
Omnicare	OCR	NYSE	56	Nursing home pharmacy gets 50% of sales from Medicaid/Medicare; expanding in infusion business
Pharmacia-Upjohn	PNU	NYSE	43⅜	Cancer drugs approx. 9% of drug sales
Physician Practice Management	PHYN	NNM	49¾	45% of revenues from Medicare/ Medicaid; chemo drugs a big profit center
ReTech	ROTC	NNM	19⅜	50% of revenues Medicare/Medicaid; 6% from chemo and nutrition therapy

It's not rocket science; what's taken them so long?"

Some of the inspector general's investigators believe they've been played for fools. "We trusted the industry and the providers," says one investigator, off the record. "We didn't know how pervasive the discounting was. We thought it was available to just select providers."

Now, the Justice Department is serving "civil investigative demands" — a kind of subpoena in antitrust investigations — on manufacturers, asking them how those inaccurate AWPs wind up in the *Red Book* and *Blue Book*.

Baxter has received one, according to investigators, for its intravenous solutions, whose true wholesale prices — like those of rival Abbott — seemito be 90% below the average wholesale price. Baxter wouldn't comment to *Barron's*.

If most health-care providers can get much lower prices for pharmaceuticals than insurers do, is it any wonder that an industry wag says that "average wholesale price" really stands for "ain't what's paid"?

"The drug makers created false statements so that the doctors could make hundreds of millions of dollars," maintains an angry investigator. "If OIG doesn't get them, the Justice Department will."

Some investigators view the spreads guaranteed by extreme average wholesale prices as a kind of kickback to doctors, in violation of federal laws.

One group of infusion-industry veterans is reportedly considering attacking the problem by filing a private suit under the False Claims Act. This is the whistleblower law that allows citizens with knowledge of fraud against the government to sue on behalf of the government and share in the recovery.

Meanwhile, the cooler-headed policymakers at the inspector general's office and in HCFA are reconsidering Medicare's drug reimbursement rules. They plan to propose their changes in the Federal Register soon.

"Medicare's been paying too much for our drugs," says deputy inspector general George Grob. "We're paying the window-sticker price when everybody else wants a discount and is getting it."

Tom Alt, of HCFA's Bureau of Policy Development, notes that any savings for Medicare will mean savings for beneficiaries, who are kicking in 20% co-payments at current Medicare prices.

Any reduction in reimbursement levels probably would have some effect on the firms that enjoy the spreads between everyday low wholesale prices and the average wholesale prices at which Uncle Sam reimburses them.

That includes oncology practice-management firms like American Oncology Resources and Physician Reliance Network, which earn significant profits on the chemotherapy drugs they administer to cancer patients. Likewise, respiratory-therapy and infusion firms like American HomePatient, Apria Healthcare, Coram Healthcare, Lincare Holdings and Ro-Tech Medical, which owe their sensational profit margins, to various degrees, to their drug spreads.

Then, there are the drug makers themselves, including Abbott, Baxter, Chiron, Gensia and Immunex — all with wide AWP spreads on their generic offerings.

Dr. H. Merrick Reese, the CEO of Physician Reliance, says he doubts that HCFA plans to cut reimbursement rates for cancer drugs, which he says his firm marks up only modestly.

More likely, Medicare will go after the inhalation drugs like albuterol, says Dr. Joseph Bailes, who chairs the clinical practice committee of the American Society of Clinical Oncology.

ChemoLabs is doing what it can to ensure that the AWP tricksters start running out of fools. Located near Fort Worth Airport, Fanning's firm will supply chemotherapy drugs for insurers, shipping doses to oncologists as needed, and for a fraction of the average wholesale price.

And the most aggressive public insurers, including Medicaid programs in six states, are turning their backs on AWP.

They now base their drug payments on WAC — the Wholesale Acquisition Cost actually paid by medical-care providers.

Blue Book editor Edelstein warns, however, that this won't end the game. "Then the manufacturers will just start fooling around with that price," he warns.

For now, says Fanning, the ChemoLab pharmacist, the bonanza drug is etoposide. Someday, he expects to see a plaque saying: "This is the house that etoposide built." ■

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Lactated Ringer's Injection, 500 ml	Intravenous Sol	Baxter	11.16	1.61	86
Normasol 500 ml	Intravenous Sol	Abbott	16.86	2.04	88
Potassium Phosphate, 15 ml vial	Intravenous Sol	Abbott	5.55	0.48	91

* Unit of Pharmacia-Upjohn

Sources: 1995 Red Book; Florida Infusion; UltraCare

Blowup of chart from p. 15

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Source: Company reports

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Memorandum

Date DEC 5 1997

From June Gibbs Brown
Inspector General

Subject OIG Final Report: "Excessive Medicare Payments for Prescription Drugs," OEI-03-97-00290

To Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration

Attached is our final inspection report that compares Medicare allowances for drugs with drug acquisition prices available to the physician and supplier communities.

Medicare allowances for 22 drugs exceeded actual wholesale prices by $447 million in 1996: For the 22 drugs reviewed, Medicare payments would have been reduced by 29 percent if actual wholesale prices had been used instead of manufacturers published wholesale prices.

For more than one-third of the 22 drugs reviewed, Medicare and its beneficiaries paid more than double the actual average wholesale price available to physicians and suppliers. For every one of the 22 drugs reviewed, Medicare reimbursed more than the average actual price in both 1995 and 1996. Not only did Medicare allow more than the average price, the program reimbursed more than even the highest wholesale price for every drug.

We also found there is no consistency among carriers in establishing and updating Medicare drug reimbursement amounts. In some cases, the difference in allowed amounts for the same drug were significant.

The information in this report provides further support for a recommendation made in an earlier report entitled "Medicare Payments for Nebulizer Drugs" where we advised that the Health Care Financing Administration (HCFA) reexamine its Medicare drug reimbursement methodologies with a goal of reducing payments as appropriate. The HCFA concurred with the recommendations. In this report, we also recommended that HCFA require all carriers to reimburse a uniform allowed amount for each Common Procedural Coding System drug code.

We support HCFA's continued effort to reduce drug payments where appropriate. We do not believe that the new reimbursement methodology for prescription drugs recently adopted by Congress will curtail the excessive drug payments identified in the Medicare program.

If you have any questions or comments about this report, please call me or George Grob, Deputy Inspector General for Evaluation and Inspections, or have your staff contact Mary Beth Clarke at (202) 619-2481.

Attachment

cc:

Margaret A. Hamburg
Assistant Secretary for
Planning and Evaluation

John J. Callahan
Assistant Secretary for
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Richard J. Tarplin
Assistant Secretary
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Melissa Skolfield
Assistant Secretary for
Public Affairs

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

EXCESSIVE MEDICA TS FOR PRESCRIPT 12/97

JUNE GIBBS BROWN
Inspector General

DECEMBER 1997
OEI-03-97-00290

EXECUTIVE SUMMARY

PURPOSE

To compare Medicare allowances for prescription drugs with drug acquisition prices currently available to the physician and supplier communities.

BACKGROUND

Medicare allowances for prescription drugs increased 25 percent from $1.8 billion in 1995 to $2.3 billion in 1996. However, the number of services allowed increased only 9 percent between the two years.

Medicare does not pay for over-the-counter or many prescription drugs that are self-administered. However, the program does pay for certain categories of drugs used by Medicare beneficiaries.

On January 1, 1998, Medicare Part B will begin to reimburse covered drugs at 95 percent of the average wholesale price. Currently, Medicare carriers may determine the amounts that Medicare will pay for these drugs based on either the lower of the Estimated Acquisition Cost (EAC) or the national Average Wholesale Price (AWP). The EAC is determined based on surveys of the actual invoice prices paid for the drug. The AWP is reported in *The Red Book* and other pricing publications and databases used by the pharmaceutical industry. Historically, it has been the AWP that carriers have used to develop Medicare reimbursement for prescription drugs.

To determine if average wholesale prices paid by Medicare truly represent wholesale prices available to physicians and prescription drug suppliers, we focused on 22 drug codes representing the largest dollar outlays to the program in 1995. We then compared the Medicare allowances for these drug codes with prices available to the physician and supplier communities.

FINDINGS

Medicare allowances for 22 drugs exceeded actual wholesale prices by $447 million in 1996.

Medicare and its beneficiaries payments for the 22 drugs would have been reduced by an estimated 29 percent ($447 million of $1.5 billion) if actual wholesale prices rather than AWP's were the basis for Medicare reimbursement. Similar savings of $445 million were also identified for 1995. If the savings percentage for just the 22 drugs was applied to Medicare's allowances for all drugs, the program and its beneficiaries would have saved an estimated $667 million in 1996.

For more than one-third of the 22 drugs reviewed, Medicare allowed amounts were more than double the actual wholesale prices available to physicians and suppliers.

Medicare allowed between 2 and 10 times the actual average wholesale prices offered by drug wholesalers and group purchasing organizations for 8 of the 22 drugs reviewed. Medicare allowed at least 20 percent more than the actual average wholesale price for over 80 percent of the 22 drugs. For every one of the 22 drugs reviewed, Medicare allowed amounts were more than the actual average wholesale price in both 1995 and 1996. Not only did Medicare pay more than the actual average wholesale price, the program allowed more than the highest average wholesale price for every drug.

There is no consistency among carriers in establishing and updating Medicare drug reimbursement amounts.

Although Medicare's reimbursement methodology for prescription drugs does not provide for different payment rates based on geographical factors, the allowed amounts for individual drug codes varied among the carriers. Medicare guidelines allow carriers to update prescription drug reimbursement on a quarterly basis. However, not only did some carriers update yearly rather than quarterly but carrier allowed amounts for the same drug code differed within a single quarter.

RECOMMENDATIONS

The findings of this report provide evidence that Medicare and its beneficiaries are making excessive payments for prescription drugs. The published AWPs that are currently being used by Medicare-contracted carriers to determine reimbursement bear little or no resemblance to actual wholesale prices that are available to the physician and supplier communities that bill for these drugs.

We believe the information in this report provides further support for a previous recommendation made by the Office of Inspector General. We recommended that HCFA reexamine its Medicare drug reimbursement methodologies, with the goal of reducing payments as appropriate. Beginning in January 1998, Medicare reimbursement for prescription drugs will be 95 percent of average wholesale price. We believe that the 5 percent reduction is not a large enough decrease and that further options to reduce reimbursement should be considered.

We also believe that the variance of Medicare reimbursement for individual drug codes among carriers is inappropriate. The rate at which physicians and suppliers are paid for drugs should not depend on which carrier the providers bill. We, therefore, recommend that HCFA require all carriers to reimburse a uniform allowed amount for each HCFA Common Procedural Coding System (HCPCS) drug code. The HCFA could choose to supply all carriers with a list of average wholesale prices that it has determined represent each drug code. The carriers could then use the uniform prices to calculate payment. The HCFA could also designate one single entity to perform all

necessary calculations to determine reimbursement for each drug code on a quarterly basis. All carriers would then use this standard reimbursement amount.

AGENCY COMMENTS

The HCFA concurred with our recommendations. The HCFA's proposal in the President's 1998 budget that would have required physicians to bill Medicare the actual acquisition cost for drugs was not adopted by Congress. However, the agency states that it will continue to pursue this policy in other appropriate ways.

We support HCFA's continued pursuance of reducing drug payments where appropriate. We do not believe that the reimbursement methodology for prescription drugs recently adopted by Congress will curtail the excessive drug payments we've identified in the Medicare program. In this report we've identified Medicare allowances that were 11 to 900 percent greater than drug prices available to the physician and supplier communities.

To address the issue of uniformity among carriers, HCFA has convened a workgroup to develop an electronic file consisting of the average wholesale prices for drugs covered by Medicare. The agency reports it will distribute this file to Medicare contractors for their use in paying drug claims.

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INTRODUCTION

PURPOSE

To compare Medicare allowances for prescription drugs with drug acquisition prices currently available to the physician and supplier communities.

BACKGROUND

Medicare allowances for prescription drugs increased 25 percent from $1.8 billion in 1995 to $2.3 billion in 1996. However, the number of services allowed increased only 9 percent between the two years.

Medicare Coverage and Payment for Prescription Drugs

While Medicare does not pay for over-the-counter or many prescription drugs that are self-administered, it does pay for certain categories of drugs used by Medicare beneficiaries. Under certain circumstances, Medicare Part B covers drugs that are used with durable medical equipment or infusion equipment. Medicare will cover certain drugs used in association with dialysis or organ transplantation. Drugs used for chemotherapy and pain management in cancer treatments are also covered. The program also covers certain types of vaccines such as those for flu and hepatitis B.

Depending on the type of drug, both local carriers and four Durable Medical Equipment Regional Carriers (DMERCs) are responsible for processing claims for drugs covered under Part B of the Medicare program. The carriers are responsible for determining the allowance that Medicare will pay for these drugs.

Carriers base their current allowance rates on the regulations established in 42 Code of Federal Regulation 405.517. According to the regulations, Medicare computes an allowed amount for drugs based on either the lower of the Estimated Acquisition Cost (EAC) or the national Average Wholesale Price (AWP). The allowed amount is the price that Medicare and its beneficiaries pay a drug supplier. The EAC is determined based on surveys of the actual invoice prices paid for the drug. The AWP is determined through *The Red Book* or similar pricing publications and databases used by the pharmaceutical industry. The AWPs are mainly provided to these sources by pharmaceutical manufacturers. If a drug has multiple sources (more than one brand or generic version), the price is based on the lower of the EAC or the median of the national AWP for all generic sources. Historically, carriers have utilized AWP and not estimated acquisition cost to develop Medicare reimbursement for prescription drugs.

Drugs are billed to the Medicare program based on codes developed by the Health Care Financing Administration (HCFA). These codes are developed as part of the HCFA Common Procedure Coding System (HCPCS). The codes define the type of drug and, in most cases, a dosage amount. The codes do not indicate whether a brand

or generic version of the drug was administered; nor do the codes provide information on the manufacturer or distributor of the drug provided.

Change in Medicare Reimbursement for Prescription Drugs

In recent legislation, Congress established reimbursement for prescription drugs at 95 percent of a drug's average wholesale price. This change will be implemented on January 1, 1998.

A different proposal to change the Medicare reimbursement methodology for prescription drugs was included in the President's FY 1998 budget. The proposal provided for the amendment of 42 U.S.C. 1395u(o) to set payment for drugs not otherwise paid on a cost or prospective payment basis. The revision set payment at the lowest of: actual acquisition cost to the provider, AWP, median actual acquisition cost, or an amount otherwise determined under the Code. The actual acquisition cost was defined to include all discounts, rebates, or any other benefit in cash or in kind. This proposal was supported by HCFA but was not the version eventually adopted by Congress.

Related Work by the Office of Inspector General

This report is one of several Office of Inspector General reports concerning Medicare payments for prescription drugs. In 1996, we released a report entitled *Appropriateness of Medicare Prescription Drug Allowances* (OEI-03-96-00420) which compared Medicare drug reimbursement mechanisms with Medicaid payment mechanisms for 17 drugs and found that Medicare could achieve significant savings by adopting reimbursement strategies similar to those used by Medicaid. The OIG has also produced several reports focusing on inhalation drugs paid for by Medicare. In *Medicare Payments for Nebulizer Drugs* (OEI-03-94-00390), we found that Medicaid reimbursed albuterol sulfate and other nebulizer drugs at significantly lower prices than Medicare. In a companion report called *A Comparison of Albuterol Sulfate Prices* (OEI-03-94-00392), we found that many retail and mail-order pharmacies charge customers less for generic albuterol sulfate than Medicare's allowed price. *Suppliers' Acquisition Costs for Albuterol Sulfate* (OEI-03-94-00393) found that Medicare's allowances for albuterol sulfate substantially exceeded suppliers' acquisition costs.

The Office of Inspector General also recently issued a report on acquisition costs of brand name drugs by Medicaid pharmacies. In *Medicaid Pharmacy - Actual Acquisition Costs of Prescription Drug Products for Brand Name Drugs* (A-06-96-00030), the Office of Audit Services estimated that the actual acquisition cost for brand name drugs was 18 percent below AWP.

METHODOLOGY

To determine if average wholesale prices paid by Medicare truly represent wholesale prices available to physicians and prescription drug suppliers, we focused on drug

codes representing the largest dollar outlays to the program in 1995. We then compared the Medicare allowances for these drug codes with prices available to the physician and supplier communities.

We collected from three sources the data needed to compare Medicare allowed amounts to actual wholesale prices. For information on Medicare allowances for prescription drugs, we compiled statistics from HCFA's National Claims History (NCH) File. We then collected Medicare reimbursement rates for specific drugs from contracted carriers. Lastly, we analyzed wholesale prices from drug wholesalers and group purchasing organizations.

Medicare Allowance Data for Prescription Drugs

We decided to review the 30 drug codes with the highest Medicare allowances for 1995. We chose 1995 since the Medicare claims data was 98 percent complete at the commencement of the inspection. To determine the Medicare allowances for prescription drugs in 1995, we compiled a list of HCPCS codes that represent all of the drugs which Medicare reimburses. The drug code list primarily contained HCPCS codes beginning with a J (known as J codes) which represent mainly injectable drugs or drugs used in conjunction with durable medical equipment. Also included in our list of drugs were K codes which usually represent immunosuppressive drugs, Q codes which represent mainly drugs used for End Stage Renal Disease, several A codes that represent drugs used for diagnostic imaging, and immunization or vaccine codes that are represented by a five digit numeric code.

We then retrieved NCH allowance and utilization data using HCFA's Part B Extract and Summary System (BESS). We aggregated the allowances for each code to calculate Medicare's total prescription drug allowance for 1995. We then determined the 30 drug codes with the highest individual allowances for that year.

Using NCH data, we calculated the Medicare allowances for all drugs in 1996. We also determined the 1996 allowances for the 30 drug codes with the highest allowances in 1995. At the time of our inspection, the NCH data for 1996 was 95 percent complete.

Carrier Allowances for Prescription Drugs

We sent requests for carrier drug reimbursement rates to Medicare's 26 fraud information specialists. The fraud information specialists coordinate work among all HCFA contractors in the regions they represent. There are a total of 61 geographical regions that local carriers cover. We received drug allowances from 50 of the 61 areas. We also received responses from two of the four DMERCS.

We requested allowed amounts for prescription drug codes with the highest total allowances in 1995. The allowed amount reflects the dollar reimbursement that Medicare will allow for the specific dosage defined by the HCPCS drug code. We

asked the carriers to provide allowed amounts by quarter for calendar years 1995, 1996, and 1997. However, some carriers provided us with data on a yearly basis and others only for certain quarters.

Some carriers also furnished allowed amounts for both participating and non-participating physicians. Physicians participating in the Medicare program agree to accept Medicare allowed amounts as total reimbursement for their services. Participating physicians receive 5 percent more in Medicare reimbursement for services. In the instances where both participating and non-participating allowed amounts were provided, we used the participating physician allowed amounts. More than three-quarters of physicians across the nation now participate in the Medicare program.

Utilizing the data provided by carriers, we calculated an average Medicare allowed amount for each drug code by year. These allowed amounts were used to compare Medicare reimbursement with drug acquisition costs for physicians and suppliers.

Prescription Drug Costs for Physicians and Suppliers

In order to determine acquisition costs for the top drugs, we reviewed 1995 and 1996 prices offered by wholesale drug companies and group purchasing organizations (GPOs). We obtained pricing lists/catalogs for seven wholesale drug companies and seven group purchasing organizations. Group purchasing organizations provide members with lower cost products by negotiating prices for specific drugs from manufacturers. The member can then purchase drugs at the negotiated price either directly from the manufacturer or a drug wholesaler that agrees to accept the negotiated price. For the GPOs we reviewed, most of the major drug wholesalers accept the GPO contracted price.

The 14 pricing sources we used provided pharmaceutical products mainly to physician practices and specialized or closed pharmacies. Depending on individual State licensing practices, specialized or closed pharmacies normally do not provide retail prescription drug dispensing to walk-in customers. Instead, they often provide prescription drugs for home infusion or inhalation therapy.

After beginning our review of wholesale drug costs, we determined that 2 of the top 30 drugs codes we identified for 1995 could not be used for the inspection. Code J7699 represents not-otherwise-classified inhalation drugs and Code J7190 for Factor VIII (human anti-hemophilic factor) has a dosage requirement that is difficult to determine. Therefore, obtaining wholesale prices for these two codes would not be possible.

For the remaining 28 drug codes identified for our analysis, 17 were used for the treatment of cancer/leukemia, 5 were inhalation drugs, 2 were vaccines, and 2 were used for organ transplantation or valve replacement complications. There was also a drug used for immunodeficiencies and another for severe infections. The majority of

these drugs would most likely be purchased and administered by physicians or other health care practitioners. The inhalation drugs or drugs used for home infusion would most likely be provided by a specialized pharmacy or supplier.

For the 28 drug codes, we collected 1995 and 1996 prices from the 14 drug pricing lists/catalogs. We decided not to present prices for drugs where fewer than two different pricing sources could be identified per year. There were 6 codes that did not meet the two source minimum. These codes were: vaccine codes 90724 and 90732, inhalation codes J7645 and J7660, and codes K0121 and J1245 used for transplants/valve replacements. A list of the HCPCS codes' descriptions and dosages for the final 22 drugs used for our evaluation is provided in Appendix A.

The 22 drug codes represented 10 single-source, 9 multiple-source, and 3 multiple-brand drugs. A single-source drug has only one brand of drug available. A multiple-source drug has both brand and generic forms of the drug available. There were no drug products manufactured in the dosage defined by the HCPCS code for five drugs (J7620, Q0136, J2405, J9181, J9293). We selected all the drugs with higher dosages that met the drug description and applied a conversion factor to achieve prices for the HCPCS-specified dosage. For an additional code (J1561), we found that out of the multitude of prices we could find for the drug only three met the exact dosage requirement. Since the higher dosage products seemed to be the more prevalent way of purchasing this drug, we included them in our analysis.

We searched the 14 price lists for both brand and generic prices during 1995 and 1996. For nine drug codes, we obtained between 5 and 8 separate prices. Eight of the nine were single-source drugs. For another eight codes, we found between 12 and 29 separate prices. We found between 30 and 70 separate prices for the remaining five drug codes.

Calculation of Potential Medicare Savings for Prescription Drugs

To determine the potential savings to Medicare if acquisition costs rather than published AWPs were used for reimbursement, we compared Medicare's allowed amounts to the wholesale prices we collected. To do this, we compiled all the pricing information from the sources reviewed and calculated an average price by year for all 22 codes. We believe that the pricing information supplied by the drug wholesalers and group purchasing organizations provides factual evidence of acquisition costs available to physicians and suppliers.

The average price or average acquisition cost for each drug code was then compared to the average Medicare allowed amount that we calculated from the carrier data. For each drug code, the difference between the average price and the Medicare allowed amount was computed. We then applied this amount to the number of services paid by Medicare for each drug in 1995 and 1996. The resulting dollar amounts were aggregated to determine the total estimated savings to Medicare if acquisition costs rather than AWP had been used to determine reimbursement.

Appendix B provides the average Medicare allowed amounts and actual average wholesale prices computed for the 22 drug codes reviewed. Although we utilized the actual average wholesale price to report savings in the findings section of this report, the appendices also contains the potential savings to Medicare if the lowest and highest wholesale prices found were compared to the Medicare allowed amount.

FINDINGS

MEDICARE ALLOWANCES FOR 22 DRUGS EXCEEDED ACTUAL WHOLESALE PRICES BY $447 MILLION IN 1996.

Medicare carriers now base prescription drug reimbursement on published average wholesales price of drugs. However, physicians and suppliers are often able to purchase drugs for prices that are much lower than the official AWPs provided by manufacturers.

After reviewing wholesale drug catalogs and group purchasing organizations' prices for the 22 drugs, we estimated that $447 million would have been saved by Medicare and its beneficiaries if Medicare had based reimbursement on actual wholesale prices rather than published AWPs in 1996. These wholesale prices are available to physicians, specialized pharmacies, and other suppliers. These wholesale prices represent the actual acquisition costs to physicians and suppliers that bill Medicare for these drugs.

Total allowed charges for the 22 drugs would have been reduced by 29 percent ($447 million of $1.5 billion) if actual wholesale prices rather than AWP were the basis for Medicare reimbursement. The 22 drugs represented 67 percent of the $2.3 billion in total Medicare drug allowances for 1996. If the savings percentage for just the 22 drugs was applied to Medicare's reimbursement for all drugs, the program and its beneficiaries would have saved an estimated $667 million in 1996.

The savings for individual drugs ranged from 13 percent of allowances for three drugs (J9202, Q0136, J9185) to a high of 92 percent for leucovorin calcium (J0640). Almost half of the drugs (10 of 22) had estimated savings greater than 40 percent of allowances. A table provided in Appendix C lists the 1996 allowances and estimated savings for the 22 drugs. The table also lists the percentage of allowance saved for each individual drug if reimbursement had been based on the actual average wholesale prices available for the drug.

Similar savings of $445 million were identified for 1995.

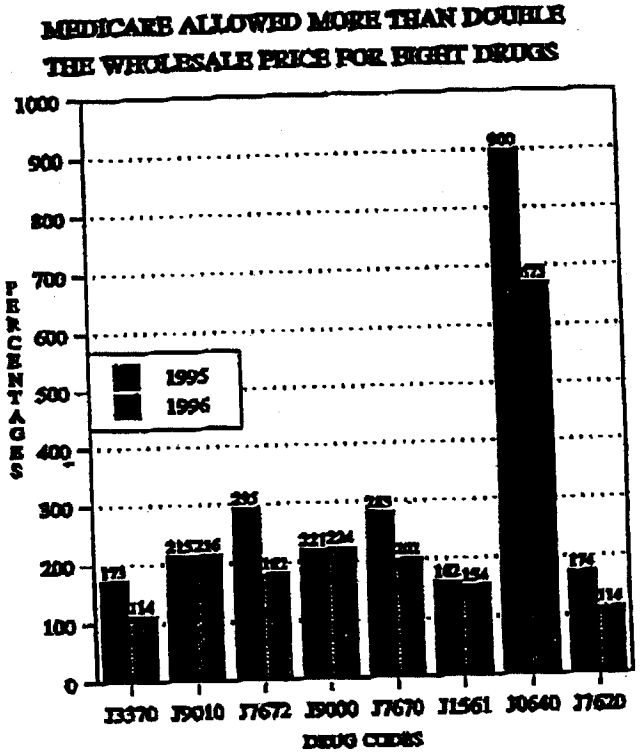
If Medicare had based reimbursement on actual wholesale costs in 1995, the program and its beneficiaries would have saved an estimated 35 percent in payments for the 22 drugs. This would have amounted to savings of $445 million on $1.3 billion in total 1995 program expenditures for these drugs. The $1.3 billion in expenditures for the 22 drugs represented 70 percent of the $1.8 billion in Medicare total drug allowances for 1995.

The percentage of allowance saved for individual drugs ranged from 15 percent for carboplatin (J9405) and fludarabine phosphate (J9185) to 95 percent for leucovorin calcium (J0640). Half of the drugs (11 of 22) had estimated savings greater than 40

percent of their 1995 allowances. Individual drug allowances and savings for 1995 are presented in Appendix C.

FOR MORE THAN ONE-THIRD OF THE 22 DRUGS REVIEWED, MEDICARE ALLOWED AMOUNTS WERE MORE THAN DOUBLE THE ACTUAL AVERAGE WHOLESALE PRICE AVAILABLE TO PHYSICIANS AND SUPPLIERS.

Medicare allowed between 2 and 10 times the actual average wholesale prices offered by drug wholesalers and group purchasing organizations for 8 of the 22 drugs reviewed. For one drug, Medicare allowed 900 percent more than the average price available for the drug in 1995 and 673 percent more in 1996. The chart below provides the percentage of the Medicare allowed amount that is greater than the actual average wholesale price for each of the eight drugs.



Medicare allowances were also significantly higher than acquisition costs for the remaining 14 drugs reviewed. Medicare allowed 60 to 95 percent more than the actual average wholesale price for 3 drugs in 1995 and 2 drugs in 1996. Medicare allowed amounts were higher by 20 to 50 percent for 9 drugs in 1995 and 8 drugs in 1996. Reimbursement was between 11 and 18 percent more for the remaining 2 drugs in 1995 and 4 drugs in 1996.

Medicare and its beneficiaries paid at least 20 percent more than the actual average wholesale price for over 80 percent of the 22 drugs. For every one of the 22 drugs reviewed, Medicare allowed more than the average actual price in both 1995 and 1996. Not only did Medicare pay more than the average price, the program allowed more than even the highest wholesale price obtained for every drug. Appendix B provides information on the highest and lowest wholesale price available for each drug in 1995 and 1996.

Based on the differences found between Medicare allowed amounts and actual wholesale prices, it is apparent that the current Medicare reimbursement methodology is based on an significantly inflated AWP statistic which bears little resemblance to actual wholesale prices available in the marketplace.

THERE IS NO CONSISTENCY AMONG CARRIERS IN ESTABLISHING AND UPDATING MEDICARE DRUG REIMBURSEMENT AMOUNTS.

Although Medicare's reimbursement methodology for prescription drugs does not provide for different payment rates based on geographical factors, the allowed amounts for individual drug codes varied among the carriers. Medicare guidelines allow carriers to update prescription drug reimbursement on a quarterly basis. However, not only did some carriers update yearly rather than quarterly but carrier allowed amounts for the same drug code differed within a single quarter.

For some drug codes, the differences in allowed amounts were significant. Carriers' allowed amounts varied even for single-source drugs where the reimbursement rate is based on only one AWP. A carrier reimbursed code J9217 (leuprolide acetate, a single-source drug) at $496.25 for all of 1995. Another carrier allowed $412.29 for the first quarter of 1995, $439.30 for the second and third quarters, and $477.50 for the fourth. For the first quarter of 1995, providers in one State were receiving 20 percent more in reimbursement than providers billing the same drug code in another State. The second carrier eventually paid $496.26 for this code in the first quarter of 1996. However, the first carrier increased reimbursement to $515.63 in the same quarter.

Little uniformity was found among carriers when comparing changes in reimbursement from the first quarter of 1995 to the second quarter of 1997. One carrier's reimbursement for code J9000 (doxorubicin hcl, 10 mg.) increased 128 percent from $20 to $45.50. Another carrier's rate for the same code decreased 19 percent from $48.20 to $39.10.

Since Medicare does not allow geographical differences to effect drug reimbursement, variations would seem to be caused by carriers' decisions regarding when to update reimbursement, what sources to use for documenting AWPs, and in the case of multiple-source drugs which generic drugs to include in calculating the median statistic.

RECOMMENDATIONS

The findings of this report provide evidence that Medicare and its beneficiaries are making excessive payments for prescription drugs. The published AWPs that are currently being used by Medicare-contracted carriers to determine reimbursement bear little or no resemblance to actual wholesale prices that are available to the physicians and suppliers that bill for these drugs. By basing reimbursement on published AWPs rather than more appropriate acquisition or wholesale prices, we estimate that Medicare and its beneficiaries paid nearly one billion dollars more for 22 drugs in 1995 and 1996.

We believe the information in this report provides further support for a previous recommendation made by the Office of Inspector General. We recommended that HCFA reexamine its Medicare drug reimbursement methodologies, with the goal of reducing payments as appropriate. The HCFA concurred with the recommendation. We urge readers to review our prior report, *Medicare Payments for Nebulizer Drugs*, which provided the full text of HCFA's comments on our recommendation.

For our readers' convenience, the options for changing Medicare's reimbursement methodology that appeared in the recommendation are presented below. We have modified the original discounted AWP and acquisition cost options in response to the evidence presented in this report concerning the large disparity between published AWPs and actual average wholesale prices available for prescription drugs.

Options for Changing Medicare's Reimbursement Methodology for Prescription Drugs

Discounted Wholesale Price

Beginning in January 1998, Medicare will reimburse prescription drugs at 95 percent of AWP. Many State Medicaid agencies use greater discounted AWPs to establish drug prices. Medicare could also base its drug payments on this larger discounted average wholesale prices. We believe that the 5 percent discount that will soon be implemented is not a large enough decrease. Upon implementation of this option, some type of general limit should be applied to the prices to ensure that inappropriate increases in average wholesale prices that could occur in subsequent years do not adversely affect Medicare payments. In addition, the Secretary should be granted the authority to conduct sample surveys of actual wholesale prices to determine the amount of difference between actual average wholesale prices and published AWPs. The percentage difference found in the sample could then be applied to all AWPs used by the program to determine drug reimbursement.

Acquisition Cost

Medicare could base the payment of drugs on either actual or estimated acquisition costs. Although Medicare currently has the authority to use EAC, carriers have yet to

successfully implement the option. Upon implementation of either the actual or estimated method, we believe that some type of general limit should be applied to ensure that inappropriate increases in drug prices do not occur in subsequent years.

Manufacturers' Rebates

Medicare could develop a legislative proposal to establish a mandated manufacturers' rebate program similar to Medicaid's rebate program. We recognize that HCFA does not have the authority to simply establish a mandated manufacturers' rebate program similar to the program used in Medicaid. Legislation was required to establish the Medicaid rebate program, and would also be required to establish a Medicare rebate program. We have not thoroughly assessed how a Medicare rebate program might operate, what administrative complexities it might pose, or how a Medicare rebate program might differ from a Medicaid rebate program. We believe, however, the legislative effort would be worthwhile. The same manufacturers that provide rebates to Medicaid make the drugs that are used by Medicare beneficiaries and paid for by the Medicare program.

To implement this option, HCFA would have to revise Medicare's claims coding system which does not identify the manufacturer or indicate if the drug is a brand name or a generic equivalent, information that is needed to discount the AWP and obtain a rebate for a specific drug. Medicaid uses National Drug Codes (NDC) in processing drug claims. The NDC identifies the manufacturer and reflects whether the drug is a brand name or a generic equivalent.

Competitive Bidding

Medicare could develop a legislative proposal to allow it to take advantage of its market position. While competitive bidding is not appropriate for every aspect of the Medicare program or in every geographic location, we believe that it can be effective in many instances, including the procurement of drugs. Medicare could ask pharmacies to compete for business to provide Medicare beneficiaries with prescription drugs. All types of pharmacies could compete for Medicare business, including independents, chains, and mail-order pharmacies.

Inherent Reasonableness

Since Medicare's guidelines for calculating reasonable charges for drugs result in excessive allowances, the Secretary can use her "inherent reasonableness" authority to set special reasonable charge limits. If this option is selected, however, it will not be effective unless the Secretary's authority to reduce inherently unreasonable payment levels is streamlined. The current inherent reasonableness process is resource intensive and time consuming, often taking two to four years to implement. Medicare faces substantial losses in potential savings--certainly in the millions of dollars--if reduced drug prices cannot be placed into effect quickly.

We also believe that the variance of Medicare reimbursement for individual drug codes among carriers is inappropriate. The rate at which physicians and suppliers are paid for drugs should not depend on which carrier providers bill. We, therefore, recommend that HCFA require all carriers to reimburse a uniform allowed amount for each HCPCS drug code. The HCFA could choose to supply all carriers with a list of average wholesale prices that it has determined represent each drug code. The carriers could then use the uniform prices to calculate payment. The HCFA could also designate one single entity to perform all necessary calculations to determine reimbursement for each drug code on a quarterly basis. All carriers would then use this standard reimbursement amount.

AGENCY COMMENTS

The HCFA concurred with our recommendations. The HCFA's proposal in the President's 1998 budget that would have required physicians to bill Medicare the actual acquisition cost for drugs was not adopted by Congress. However, the agency states that it will continue to pursue this policy in other appropriate ways. The full text of HCFA's comments are provided in Appendix D.

We support HCFA's continued pursuance of reducing drug payments where appropriate. We do not believe that the reimbursement methodology for prescription drugs recently adopted by Congress will curtail the excessive drug payments we've identified in the Medicare program. In this report we've identified Medicare allowances that were 11 to 900 percent greater than drug prices available to the physician and supplier communities.

To address the issue of uniformity among carriers, HCFA has convened a workgroup to develop an electronic file consisting of the average wholesale prices for drugs covered by Medicare. The agency reports it will distribute this file to Medicare contractors for their use in paying drug claims.

APPENDIX A

Description of 22 HCPCS Codes

Code	Description
J9217	Leuprolide Acetate (for depot suspension), 7.5 mg.
J7620	Albuterol Sulfate, 0.083%, per ml., inhalation solution administered through DME
J9265	Paclitaxel, 30 mg.
J9202	Goserelin Acetate Implant, per 3.6 mg.
J0640	Injection, Leucovorin Calcium, per 50 mg.
J9045	Carboplatin, 50 mg.
J1440	Injection, Filgrastim (G-CSF), per 300 mcg.
Q0136	Injection, Epoetin Alpha, (For Non-ESRD Use), per 1000 units
J2405	Injection, Ondansetron Hydrochloride, per 1 mg.
J1625	Injection, Granisetron Hydrochloride, per 1 mg.
J1561	Injection, Immune Globulin, Intravenous, per 500 mg.
J7670	Metaproterenol Sulfate, 0.4%, per 2.5 ml., inhalation solution administered through DME
J1441	Injection, Filgrastim (G-CSF), per 480 mcg.
J9182	Etoposide, 100 mg.
J9000	Doxorubicin HCL, 10 mg.
J9031	BCG (Intravesical) per instillation
J9181	Etoposide, 10 mg.
J7672	Metaproterenol Sulfate, 0.6%, per 2.5 ml., inhalation solution administered through DME
J9293	Injection, Mitoxantrone Hydrochloride, per 5 mg.
J9185	Fludarabine Phosphate, 50 mg.
J9010	Doxorubicin HCL, 50 mg. (code discontinued 12/31/96)
J3370	Injection, Vancomycin HCL, up to 500 mg. (code discontinued for infusion 9/1/96)

APPENDIX B

SUMMARY OF WHOLESALE PRICES AND ESTIMATED SAVINGS FOR 1995 AND 1996

SUMMARY OF WHOLESALE PRICES AND ESTIMATED SAVINGS FOR 1995

HCPCS Code	Average Medicare Allowed Amount	Actual Average Wholesale Price	Savings Based on Actual Average Wholesale Price	Lowest Wholesale Price Found	Savings Based on Lowest Wholesale Price	Highest Wholesale Price Found	Savings Based on Highest Wholesale Price
J9217	$474.67	$394.33	$83,728,802	$391.00	$87,202,882	$396.00	$81,991,762
J7620	$0.42	$0.15	$106,352,439	$0.12	$119,040,331	$0.21	$85,081,951
J9265	$180.82	$148.70	$14,425,220	$146.10	$15,592,891	$150.00	$13,841,385
J9202	$353.82	$292.95	$11,716,412	$286.84	$12,891,775	$296.00	$11,128,731
J0640	$23.27	$2.33	$61,175,769	$1.89	$62,449,291	$2.90	$59,499,161
J9045	$78.01	$66.67	$7,226,520	$64.90	$8,352,014	$67.55	$6,663,773
J1440	$149.46	$124.47	$8,620,001	$124.20	$8,711,972	$125.00	$8,436,058
Q0136	$11.92	$9.92	$7,942,246	$8.84	$12,246,366	$10.70	$4,850,833
J2405	$5.65	$4.33	$10,591,319	$3.91	$14,012,161	$5.31	$2,712,031
J1625	$165.29	$123.58	$9,709,625	$117.00	$11,240,029	$132.80	$7,562,405
J1561	$42.21	$16.12	$23,539,871	$9.33	$29,422,574	$32.11	$9,036,521
J7670	$1.22	$0.32	$23,986,743	$0.26	$25,544,703	$0.40	$21,872,652
J1441	$234.96	$195.50	$5,256,151	$188.90	$6,135,284	$198.80	$4,816,584
J9182	$131.25	$76.70	$11,660,930	$56.00	$16,085,515	$113.55	$3,783,570
J9000	$42.14	$13.12	$11,445,719	$10.90	$12,319,556	$14.70	$10,821,019
J9031	$155.20	$120.54	$3,659,236	$94.28	$6,430,898	$138.44	$1,769,236
J9181	$14.03	$7.80	$6,688,786	$5.60	$9,052,665	$11.36	$2,872,584
J7612	$1.22	$0.31	$11,560,517	$0.26	$12,175,863	$0.40	$10,400,217
J9263	$206.69	$127.49	$6,846,261	$123.23	$7,214,694	$132.01	$6,456,006
J9185	$173.03	$149.08	$1,890,949	$145.25	$2,193,648	$152.00	$1,660,634
J9040	$204.21	$64.86	$9,942,878	$52.00	$18,860,640	$73.50	$9,326,551
J3530	$10.07	$3.69	$7,235,171	$2.02	$9,122,193	$6.99	$3,491,965
TOTAL			$445,801,565		$496,297,745		$368,075,629

SUMMARY OF WHOLESALE PRICES AND ESTIMATED SAVINGS FOR 1996

HCPCS Code	Average Medicare Allowed Amount	Actual Average Wholesale Price	Savings Based on Actual Average Wholesale Price	Lowest Wholesale Price Found	Savings Based on Lowest Wholesale Price	Highest Wholesale Price Found	Savings Based on Highest Wholesale Price
J9217	$499.72	$414.73	$104,365,435	$409.27	$111,066,902	$421.00	$96,663,201
J7620	$0.41	$0.19	$92,199,355	$0.16	$105,604,026	$0.25	$67,530,255
J9265	$181.32	$148.56	$22,757,465	$140.26	$28,526,148	$155.43	$17,986,896
J9202	$378.29	$329.43	$11,215,983	$317.00	$14,067,894	$341.85	$8,364,073
J0640	$21.70	$2.81	$52,514,021	$2.99	$53,670,253	$3.45	$50,724,087
J9045	$82.76	$67.64	$12,539,724	$64.90	$14,814,584	$70.55	$10,128,000
J1440	$154.65	$123.39	$11,592,740	$121.56	$12,271,393	$126.00	$10,624,824
Q0136	$11.93	$10.37	$10,399,198	$9.31	$17,440,772	$10.70	$8,195,663
J2405	$6.08	$4.28	$14,319,348	$3.92	$17,172,050	$4.73	$10,776,959
J1625	$170.02	$125.71	$13,999,842	$122.90	$14,250,690	$128.00	$12,708,277
J1561	$42.21	$16.65	$24,808,622	$12.50	$28,833,317	$34.00	$7,967,739
J7670	$1.23	$0.41	$9,935,367	$0.32	$10,965,879	$0.51	$8,658,040
J1441	$246.34	$196.76	$8,470,488	$191.99	$9,285,542	$202.25	$7,532,512
J9182	$137.57	$70.91	$13,362,365	$37.06	$20,147,028	$112.57	$5,011,200
J9000	$44.19	$13.65	$12,480,751	$10.87	$13,616,851	$17.95	$10,723,475
J9031	$157.53	$133.13	$2,632,097	$112.00	$5,004,749	$148.95	$943,131
J9181	$14.14	$8.02	$5,909,155	$3.71	$10,077,601	$11.26	$2,784,899
J7672	$1.23	$0.44	$4,805,175	$0.32	$5,492,908	$0.55	$4,117,563
J9293	$172.81	$142.40	$2,712,650	$139.91	$2,935,141	$145.38	$2,447,586
J9185	$179.45	$156.50	$2,049,320	$152.00	$2,451,148	$161.00	$1,647,493
J9010	$207.12	$65.46	$10,513,722	$54.00	$11,364,260	$76.00	$9,731,464
J3370	$9.44	$4.42	$4,213,709	$3.45	$5,027,227	$6.45	$2,509,417
TOTAL			$447,246,532		$514,085,963		$357,776,754

APPENDIX C

INDIVIDUAL DRUG ALLOWANCES AND SAVINGS PERCENTAGES FOR 1995 AND 1996

Estimated Medicare Savings if Acquisition Costs Were Used for 1995 Prescription Drug Reimbursement

HCPCS Code	Drug Description	1995 Allowances	Estimated Savings	Percent Saved
J9217	Leuprolide Acetate	$455,238,461	$83,728,802	18%
J7620	Albuterol Sulfate 0.083%	$166,901,971	$106,352,439	64%
J9265	Paclitaxel	$79,672,417	$14,425,220	18%
J9202	Goserelin Acetate Implant	$65,806,263	$11,716,412	18%
J0640	Leucovorin Calcium	$64,687,013	$61,175,769	95%
J9045	Carboplatin	$49,306,732	$7,226,520	15%
J1440	Filgrastim, per 300 mcg.	$47,401,344	$8,620,001	18%
Q0136	Epoetin Alpha (Non-ESRD Use)	$47,324,218	$7,942,246	17%
J2405	Ondansetron Hydrochloride	$45,279,311	$10,591,319	23%
J1625	Granisetron Hydrochloride	$33,013,314	$9,709,625	29%
J1561	Immune Globulin	$31,646,866	$23,339,871	74%
J7670	Metaproterenol Sulfate 0.4%	$30,822,456	$23,986,743	78%
J1441	Filgrastim, per 480 mcg.	$29,865,814	$5,256,151	18%
J9182	Etoposide, 100 mg.	$25,713,304	$11,660,930	45%
J9000	Doxorubicin HCL, 10 mg.	$16,017,009	$11,445,719	71%
J9031	BCG (Intravesical)	$15,494,267	$3,659,236	24%
J9181	Etoposide, 10 mg.	$14,510,938	$6,688,786	46%
J7672	Metaproterenol Sulfate 0.6%	$13,876,217	$11,560,517	83%
J9293	Mitoxantrone Hydrochloride	$13,271,172	$6,846,261	52%
J9185	Fludarabine Phosphate	$12,725,400	$1,890,949	15%
J9010	Doxorubicin HCL, 50 mg.	$12,515,401	$9,942,878	79%
J3370	Vancomycin HCL	$12,051,885	$7,235,171	60%
TOTAL		$1,283,141,773	$445,001,565	35%

Estimated Medicare Savings if Acquisition Costs Were Used for 1996 Prescription Drug Reimbursement

HCPCS Code	Drug Description	1996 Allowances	Estimated Savings	Percent Saved
J9217	Leuprolide Acetate	$577,547,780	$104,365,435	18%
J7620	Albuterol Sulfate 0.083%	$175,399,846	$92,199,355	53%
J9265	Paclitaxel	$125,093,980	$22,757,465	18%
J9202	Goserelin Acetate Implant	$84,187,487	$11,215,983	13%
J0640	Leucovorin Calcium	$57,323,221	$52,514,021	92%
J9045	Carboplatin	$67,530,797	$12,539,724	19%
J1440	Filgrastim, per 300 mcg.	$54,460,250	$11,592,740	21%
Q0136	Epoetin Alpha (Non-ESRD Use)	$79,558,670	$10,399,198	13%
J2405	Ondansetron Hydrochloride	$47,331,513	$14,319,348	30%
J1625	Granisetron Hydrochloride	$49,691,403	$13,399,842	27%
J1561	Immune Globulin	$35,104,622	$24,808,622	71%
J7670	Metaproterenol Sulfate 0.4%	$14,203,070	$9,935,367	70%
J1441	Filgrastim, per 480 mcg.	$40,592,257	$8,470,488	21%
J9182	Etoposide, 100 mg.	$25,739,111	$13,362,365	52%
J9000	Doxorubicin HCL, 10 mg.	$17,410,833	$12,480,751	72%
J9031	BCG (Intravesical)	$16,544,398	$2,682,097	16%
J9181	Etoposide, 10 mg.	$13,381,243	$5,909,155	44%
J7672	Metaproterenol Sulfate 0.6%	$6,595,854	$4,805,175	73%
J9293	Mitoxantrone Hydrochloride	$14,522,607	$2,712,650	19%
J9185	Fludarabine Phosphate	$15,462,970	$2,049,320	13%
J9010	Doxorubicin HCL, 50 mg.	$14,541,250	$10,513,722	72%
J3370	Vancomycin HCL	$8,234,140	$4,213,709	51%
TOTAL		$1,540,457,302	$447,246,532	29%

APPENDIX D

HEALTH CARE FINANCING ADMINISTRATION COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Deputy Administrator
Washington, D.C. 20201

DATE: OCT - 1 1997

TO: June Gibbs Brown
Inspector General

FROM: Nancy-Ann Min DeParle NMD
Deputy Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Excessive Medicare Payments for Prescription Drugs," (OEI-03-97-00290)

We reviewed the above-referenced report that examines Medicare payments for prescription drugs. Medicare allowances for prescription drugs increased 25 percent from $1.8 billion in 1995 to $2.3 billion in 1996. However, the number of services allowed increased only 9 percent between the 2 years.

Medicare does not pay for over-the-counter drugs or many prescription drugs that are self-administered. However, the program will pay for certain categories of drugs used by its beneficiaries. Contracted carriers determine the amounts that Medicare will pay for the drugs based on the lower of the estimated acquisition cost (EAC) or the national average wholesale price (AWP). The allowed amount is the price that Medicare and its beneficiaries pay a drug supplier. OIG findings indicate that at present, it is the AWP that carriers use to develop Medicare reimbursement for prescription drugs. The AWP is reported in The Red Book and other pricing publications and databases used by the pharmaceutical industry. The EAC is determined based on surveys of the actual invoice prices paid for the drug.

The findings contained in the report indicate that Medicare is making excessive payments for prescription drugs. The published AWPs currently used by Medicare carriers to determine reimbursement do not resemble the actual wholesale prices which are available to the physician and supplier communities that bill for these drugs.

OIG suggests that the Health Care Financing Administration (HCFA): (1) reexamine its Medicare drug reimbursement methodologies, with the goal of reducing payments; and (2) require all carriers to reimburse a uniform allowed amount for each HCFA Common Procedural Coding System (HCPCS) drug code.

HCFA concurs with OIG's recommendations. Our detailed comments are as follows:

OIG Recommendation 1

HCFA should require all carriers to reimburse a uniform allowed amount for each HCPCS drug code.

HCFA Response

We concur. HCFA agrees with OIG's findings and recommendations contained in this report. HCFA convened a workgroup to develop an electronic file consisting of the AWPs for drugs covered by Medicare. HCFA will then distribute this file to Medicare contractors for their use in paying claims for drugs.

OIG Recommendation 2

HCFA should reexamine its Medicare drug reimbursement methodologies, with the goal of reducing payments as appropriate.

HCFA Response

We concur. We agree with OIG's findings and recommendations. We included a provision in the President's 1998 budget bill that would have eliminated the markup for drugs billed to Medicare by requiring physicians to bill the program the actual acquisition cost for drugs. Unfortunately, this provision was not enacted, but we will pursue this policy in other appropriate ways.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456
	CIVIL ACTION NO. 01-CV-12257-PBS
	Judge Patti B. Saris
THIS DOCUMENTS RELATES TO ALL ACTIONS	

DEFENDANT BRISTOL-MYERS SQUIBB COMPANY'S
LOCAL RULE 7.3 DISCLOSURE STATEMENT

Pursuant to Local Rule 7.8, the undersigned attorney of record for defendants Bristol-Myers Squibb Company ("BMS"), Oncology Therapeutics Network Corporation ("OTN") and Apothecon, Inc. hereby certifies that BMS is a publicly-held corporation with no parent companies and that no publicly held corporation owns 10% or more of BMS' outstanding stock. The undersigned attorney also certifies that OTN and Apothecon, Inc. are wholly owned subsidiaries of BMS.

New York, New York
November 4, 2002

HOGAN & HARTSON L.L.P.

By: _____
Lyndon M. Tretter

875 Third Avenue
New York, New York 10022
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Attorneys for Defendants
Bristol-Myers Squibb Company, Oncology Therapeutics Network Corporation and Apothecon, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CITIZENS FOR CONSUMER JUSTICE ET AL., Plaintiffs, v. ABBOTT LABORATORIES, INC. ET AL., Defendants. AND ALL RELATED CASES	Civil Action No. 01-12257-PBS MDL No. 1456

CERTIFICATE OF COMPLIANCE WITH LOCAL RULE 7.1

Pursuant to Local Rule 7.1 (A)(2), I hereby certify that counsel for Defendant Bristol-Myers Squibb has conferred in good faith with counsel for Citizens for Consumer Justice, Edward Notargiacomo of Hagens Berman LLP, by telephone on November 4, 2002 for the purposes of attempting to resolve the issues addressed in the Motion to Dismiss. The efforts were unsuccessful.

Respectfully submitted,

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Dated: November 4, 2002

CERTIFICATE OF SERVICE

I, Lyndon M. Tretter, certify that a true and correct copy of the following was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on Nov. 4, 2002, a copy to Verilaw Technologies for posting and notification to all parties:

Defendant Bristol-Myers Squibb Company's Rule 7.3 Corporate Disclosure;

Notice of Appearance for Defendant Bristol-Myers Squibb Company; and

Motion for Admission Pro Hac Vice.

Lyndon M. Tretter